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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/666,154

09/19/2003

Bryan Windus-Smith

DDI-5016

8222

27777 7590 04/16/2008
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EXAMINER

REYNOLDS, STEVEN ALAN

ART UNIT

PAPER NUMBER

3728

MAIL DATE

DELIVERY MODE

04/16/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/666,154	WINDUS-SMITH ET AL.	
	Examiner	Art Unit	
	Steven Reynolds	3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 6-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 6-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/17/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/17/2008 has been entered.

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1, 2, 6-9 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Abidin et al. (US 5,528,811). Abidin discloses a medical device package comprising a main cap member (13) with a cavity therein, the main cap member including: a proximal end; and a distal end; and a minor cap member (14); a connector (scalpel handle 31); wherein the cavity has a cavity opening at the proximal end of the main cap member (opening to the left of pin 25 in Fig. 12); the cavity is capable of receiving, and to securely and removably retain, no more than a portion of (only a portion of 16 is within the cavity) a medical device with electrical contacts therein such that the electrical contacts project from the cavity opening and minor cap member, and the minor cap member is capable of sealing the cavity opening (when the cap 14 is

closed) once the medical device has been partially received in the cavity; the connector is configured to engage the medical device during removal of the medical device from the cavity and includes a strip engaging element (groove 32) capable of contacting electrical contacts; the main cap member includes at least one lateral channel (the space between pin 25 and the sidewall is considered a channel) and wherein the medical device is securely and removably retained by a friction fit between the medical device and the at least one lateral channel; the minor cap member is breachable (through opening shown in cap 14 in Figs. 7 and 8); the minor cap member is capable of permanent attachment to the medical device (if the blade 16 is never used, it remains attached to the inside surface of minor cap 14); the main cap member further includes a distal end (at 27) cavity capable of disabling the medical device; and the connector is capable of breaching the minor cap member (See Fig. 11).

Regarding the intended use of the claimed invention “configured to receive, and to securely and removably retain no more than a portion of a medical device with electrical contacts therein such that the electrical contacts project from the cavity opening and minor cap member”, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. If the prior art structure is capable of performing the intended use, then it meets the claim. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Regarding claim 13, Abidin discloses the method for extracting a medical device including the steps of providing: a medical device package with a medical device

partially contained therein, the medical device package including: a main cap member with a cavity therein, the main cap member including: a proximal end; and a distal end; a minor cap member; and wherein: the cavity has a cavity opening at the proximal end of the main cap member; the cavity is configured to receive, and to securely and removably retain, no more than a portion of a medical device with electrical contacts therein such that the electrical contacts project from the cavity opening and minor cap member; and the minor cap member is sealing the cavity opening; and a connector; breaching the minor cap member with the connector such that at least a portion of the connector has entered the cavity of the medical device cavity; engaging the medical device with the connector; and extracting the connector and engaged medical device from the cavity of the medical device package.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abidin et al. (US 5,528,811). As described above, Abidin discloses the claimed invention except for the steps of reinserting the connector and engaged medical device back into the cavity whereby the medical device is disabled from subsequent use. Official Notice is taken that it is old and conventional to use a blade package as a dispenser and then a disposal for the used blade. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made in view of

the Official Notice to reuse the package of Abidin to dispose of the medical device after use in order to protect the used blade from the environment.

6. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abidin et al. (US 5,528,811) in view of Vidal et al. (US 4,903,390). As described above, Abidin discloses the claimed invention except for the directional marker on the main cap member. However, Vidal et al. teaches a medical device package comprising a main cap member including an arrow (61) for the purpose of indicating that the scalpel is to be inserted with the cutting edge of the blade extending upwardly. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the main cap member of Abidin with an arrow as taught by Vidal et al. to indicate to the user which direction to insert the connector into the cavity.

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abidin et al. (US 5,528,811) in view of Newman et al. (US 2002/0143352). As described above, Abidin discloses the claimed invention except for the specifics of the connector. However, Newman et al. teaches a connector (scalpel handle) comprising a shield (40) slidably mounted to the scalpel to prevent inadvertent access to the blade, including arrows (28) on the scalpel for the purpose of visual indication to the user of the direction in which the shield should be moved. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the connector (scalpel handle) of Abidin with the shield and arrows as taught by Newman et al. in order to shield the medical device (blade) when not in use.

8. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abidin et al. (US 5,528,811) in view of Charlton (US 2003/0036200). As described above, Abidin discloses the claimed invention except for the specifics of the medical device. However, Charlton teaches a medical device (test sensor 120) comprising a tissue penetration member and a test strip for the purpose of collecting and testing a sample of blood. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the medical device package of Abidin to store the medical device as taught by Charlton in order to safely dispose the used medical device.

Response to Arguments

9. Applicant's arguments with respect to claims 1-3 and 6-18 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Reynolds whose telephone number is (571)272-9959. The examiner can normally be reached on Monday-Friday 9:00am - 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571)272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mickey Yu/
Supervisory Patent Examiner, Art
Unit 3728

/S. R./
Examiner, Art Unit 3728